04-19-05

traversed for the following reasons. The Examiner correctly states that Yamamoto does not teach or suggest the use of polyvinyl alcohol as required by Claim 1 of the present invention. The Examiner also states that Jansen teaches a method for producing capsules in which the encapsulating composition can be polyvinyl alcohol (broad disclosure of the use of PVA at Column 5, line 54 without any discussion of amount or co-system). The Examiner's attempt to combine Yamamoto and Jansen fails because the Examiner confuses Yamamoto's use of cellulose ethers which are different chemically from Jansen's use of cellulose esters. Furthermore, Jansen requires a liquid fill seamless capsule which is congealed by contact with an oil coolant into a final product. Jansen's technology is not relevant to the present invention and, in fact, does not teach compositions that are suitable for molding with later filling of the capsule. Finally, the technologies described in Yamamoto and Jansen are not remotely related in any way that would cause one skilled in the art to look to one reference and fill in the missing pieces from the other reference. One skilled in the art would not look to a liquid filled, one-piece product gelled in a single step to envelope its liquid contents in a single capsule in order to select Ingredients for a two piece capsule which is molded and then air dried.

The fact that Yamamoto fails to disclose or suggest the use of PVA also means that the Examiner's attempt to use the disclosure of hydrocolloids and cations in Yamamoto is not sufficient to teach the present invention. The Examiner has failed to find a combination of references that in fact make sense to combine. The random selection of gelling agents from references without regard to the technologies being described is not sufficient to negate patentability. This approach is simply hindsight reconstruction which has been repeatedly rejected by the courts as not being the appropriate standard for evaluating patentability.

The present invention is made from a particular combination of polyvinyl alcohol, a hydrocolloid and cations. There is no teaching or suggestion in Yamamoto and Jansen alone or in combination that would result in a person skilled in the art combining their teachings to obtain the instant invention as described in the pending claims.

In Paragraph 5 of the Office Action, the Examiner rejects Claims 58-59 under 35 USC 103(a) on the basis of Yamamoto in view of Jansen as applied above to Claims 57, 60-61, 67-70, and 78-81, and further in view of Deters et al (USP 4,627,850). This rejection is traversed for the reasons described above and also because the invention in Deters requires two layers (lamina) as a water swellable material and a semi-permeable material. The examples of Deters describe gelatin capsules. The drug delivery in Deters is based on structured coating with an orifice through the lamina and the capsule. The coating described in Deters is for an osmotic product with delayed release of active. Any use of PVA appears to be limited to a separate lamina coating and not combined with other ingredients except for the plasticizers listed in column 9, lines 65-68. Furthermore, there is no teaching or disclosure of a capsule made with the types and amounts of ingredients as currently described in the pending claims, including the cation component.

In Paragraph 6 of the Office Action, the Examiner indicates that Claims 63-65 would be allowable if rewritten in Independent from including all of the limitations of the base claim and any intervening claims. Applicant's attorney gratefully acknowledges this point but is requesting the Examiner to consider the above comments to add additional allowable claims to this case.

It is respectfully submitted that the rejections have been overcome for the reasons explained above and on the basis of the Amendment listed herein. An early Notice of Allowability is respectfully requested.

6512-11

It is suggested that the Examiner contact the undersigned attorney at the number listed below to further discuss the points recited above.

Apr. 18,2085

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Respectfully submitted

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